REMARKS

This Amendment corrects typographical errors made in the reproduction of portions of pages 4-6, 8-9, 12-14 of the amended specification in the Amendment filed March 3, 2009. The amendments and remarks are otherwise identical to the March 3, 2009 Amendment.

Claims 1-10 have been examined. New claim 11 has been added by amendment above. Support for new claim 11 can be found in claim 1 as previously presented. Claims 1, 2, 4, 5 and 8 have been amended above to correct obvious typographical errors and to clarify the language of the claims. No new matter has been introduced through any of these amendments.

In the outstanding Office Action, the examiner objected to the specification because of typographical errors on pages 4 and 11 and because trademarks were improperly referenced. Appropriate corrections have been made. Additional typographical errors on page 5 also have been corrected by amendment above.

Claim 2 has been objected to due to a spelling error in the claim. That error has been corrected by amendment above.

Claims 1 and 4-6 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the examiner asserted that claim 1 as currently written is vague in its recitation of "which can be obtained by." This rejection has

been obviated by the amendment to claim 1 above. In addition, the examiner found claim 4 to be indefinite in its recitation of "substantially free." The examiner asserted that this term is not defined in the claim, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention as set forth in claim 4. This rejection is traversed.

The water soluble glucans of the cosmetic preparations of the invention are discussed on page 3 of the specification. The specification provides that the glucans

> are substantially free from undesired (1,6) linkages. Preferably such β-(1,3) glucans are used where the side chains exclusively show (1,3) linkages. ... Glucans of thus type are available in technical amounts according to known methods. The international patent application WO 95/30022 (Biotec-Mackzymal) describes a method for producing such substances, wherein glucans with β-(1,3) and β-(1,6) linkages are brought in contact with β-(1,6) glucanases in such a way that essentially all β-(1,6) linkages are loosened.

The application thus does provide guidance on what is meant by "substantially free" and it teaches that one can prepare a

product which is "substantially free" of β-(1,6) linkages by following a procedure in the cited published PCT application.

Furthermore, Applicants respectfully submit that the term "substantially free" would be well-understood by one of ordinary skill in the art and that the term is the best way of defining a complex biological molecule. A person of ordinary skill in the art would indeed know that the term means that the water-soluble β-(1,3) glucans of the invention do not have to be entirely free from β-(1,6) linkages but rather are substantially free from such linkages. The term "substantially free from" is a term in the art that is well understood to mean "to a great extent free from," but does not mean that there is a strict requirement for the species in question to be completely absent. While a detailed inspection may reveal that some of the species is present, it is present in such small quantities that for purposes intended it can be considered absent. In addition, glucans are known to be complex biochemical molecules, and the glucan of this invention typically is produced by an enzymatic process and, therefore, a strict and highly precise definition of its structure in not appropriate, as it might be if it were produced by a process which could be entirely synthetically controlled. The term "substantially" is, therefore, the appropriate language for the glucan of the invention.

The examiner asserted that claims 5 and 6 are vague in indefinite in their recitation of naphthenic hydrocarbons. The examiner asserted that Applicants have not defined "naphthenic" and that the dictionary definition of the term is that such hydrocarbons are cyclic. As such, the examiner questioned how the claims could refer to linear naphthenic compounds. Applicants have clarified the language of the claims above.

Claims 1-4 and 7-8 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Cardinal et al., U.S. Patent 4,895,724, in view of Vanderhoff et al., U.S. Patent 6,214,331. The examiner asserted that Cardinal discloses a porous matrix of chitosan and a macromolecular compound, which can be a polysaccharide, such as dextran or heparin, dispersed therein. The compositions are for the controlled and prolonged release of the macromolecular compounds dispersed within the chitosan matrix, and higher amounts of cross-linking are said to lower the release rate of the macromolecular compound. The examiner noted that Cardinal does not disclose the β-(1,3) glucan feature of the compositions of the present claims, but he asserted that this deficiency is provided by Vanderhoff. The secondary reference was said to disclose a process for the preparation of aqueous dispersions of particle of water-soluble polymers, wherein cross-linking agents are used to cross-link the functional groups of

the polymers. Useful polymers include polysaccharides such as curdlan, which is a β-(1,3) glucan. The examiner asserted that it would have been obvious to combine the teachings of the two references to use curdlan in the invention of Cardinal to arrive at the present invention. This rejection is traversed.

As an initial, and significant, point, Applicants note that the present invention is based upon the properties of an integrated and covalently linked matrix of two types of biomolecule, which is very different from the product of Cardinal in which a "porous matrix" of chitosan is provided in which any target macromolecule can be "dispersed" (as described in the abstract of the patent). Cardinal does not describe or suggest cross-linking of the chitosan to the other macromolecule. Rather, the cross-linking is internal within the chitosan matrix. Thus, cross-linking between the two species is <u>not</u> taught by Cardinal and is incompatible with the aim of slow release of the target macromolecule from the porous chitosan matrix. In contrast, in the presently claimed invention, forming links between the two species is an essential feature of the product and provides it with improved mechanical properties. In view of this, it is apparent that the Cardinal patent is not an appropriate starting point for arriving at the present invention.

As Applicants previously have pointed out, Cardinal does not disclose that the macromolecules are linked in the chitosan structure and are unable to escape, as is the case with the present invention. The whole purpose of the Cardinal compositions is to provide a slow and prolonged release of macromolecular compounds from the chitosan matrix. The examiner has rejected this argument, asserting that if the Cardinal matrix is loaded with the macromolecule prior to cross-linking (as is an option with the present invention), then the steps of preparation would be the same as those presently claimed and the macromolecule used would be locked into the chitosan structure. Applicants respectfully submit that the examiner's assumption is incorrect; Cardinal teaches that the compositions made by any of the methods he discloses would still be suitable for the controlled release of the macromolecules, i.e., the macromolecule would not be locked in. It also should be noted that the passage in column 5, lines 3-22, which discusses cross-linkers for loaded chitosan, teaches high molecular weight polysaccharide polyaldehydes and provides that these are "generally not capable of penetrating the chitosan matrix and affecting the macromolecule in the matrix." Thus, the reference teaches how cross-linking between the two components should be avoided.

The examiner also has objected to Applicants' previous arguments regarding the Cardinal reference on the basis that the "locked in" feature of the present invention is not recited in the claims. Applicants respectfully disagree; the present claims provide that the chitosans and glucans are cross-linked; this physical connection thus "locks-in" the glucan. In contrast to the polysaccharides and polypeptides disclosed in the Cardinal reference, β-glucans would be locked in to the chitosan structure due to their large and branched structure. One of skill in the art would recognize this and so would find it contrary to the teachings of Cardinal to use a β-glucan in the Cardinal compositions. As a result, one of skill in the art would not look to the Cardinal reference for a teaching on how to prepare a cross-linked chitosan composition in which the macromolecule contained therein was not released from the chitosan matrix. Although dextrans and heparin can be released from the chitosan matrix of Cardinal, β-glucans could not.

A central concept of the present invention is the structural nature of the compositions formed, i.e. the composition is a semi-solid and "machinable" material comprised of cross-linked chitosans and glucans capable of "manipulation", for example as a face mask or fleece (see page 1, lines 27 to 30 and page 2, lines 3 to 7 as well as page 19, lines 20 to 21, which indicates that

the compositions can "behave like sponges"). It is the very fact that the β-glucans are not released from the compositions due to the cross-linking and their large branched structure which is the source of these desirable properties. The Cardinal reference does not disclose a product with the properties and indeed is not even directed to the filed of cosmetics.

The shortcomings of the Cardinal reference have been discussed at length above; the secondary Vanderhoff reference does not compensate for these deficiencies. Neither reference teaches or suggests how to provide a composition with improved dermatological compatibility, immunostimulation, machinability, or flexibility, and one of skill in the art wishing to prepare an improved cosmetic composition having such properties would not look to these references or find any guidance in them should he do so.

Claims 5-6 have been rejected under 35 U.S.C. § 103(a) as unpatentable over the Cardinal and Vanderhoff references cited above in further view of U.S. Patent 4,879,340, issued to Moriguchi et al. Claim 9 has been rejected under this same section of the statute as unpatentable over the Cardinal and Vanderhoff references in further view of U.S. Patent 6,162,537, issued to Martin et al. Both of these rejections are traversed.

The shortcomings of the Cardinal and Vanderhoff references have been discussed above, and that discussion is equally applicable to the rejections of claims 5, 6 and 9. The cited tertiary references do not compensate for the deficiencies of the primary and secondary references and are insufficient to render obvious the subject matter of these claims.

In view of the foregoing amendments and discussion, Applicants respectfully submit that the pending claims are in condition for allowance.

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